

By Senator Lee

23-733-99

See HB

1 A bill to be entitled
2 An act relating to pharmacy practice; amending
3 s. 465.003, F.S.; defining the term "data
4 communication device"; revising the definition
5 of the term "practice of the profession of
6 pharmacy"; amending s. 465.016, F.S.;
7 authorizing the redispensing of unused or
8 returned unit-dose medication by correctional
9 facilities under certain conditions; providing
10 a ground for which a pharmacist may be subject
11 to discipline by the Board of Pharmacy;
12 amending s. 465.017, F.S.; providing additional
13 persons to whom and entities to which records
14 relating to the filling of prescriptions and
15 the dispensing of medicinal drugs that are
16 maintained by a pharmacy may be furnished;
17 specifying authorized uses of patient records
18 by pharmacy owners; providing restrictions on
19 such records when transmitted through a data
20 communication device; amending ss. 465.014,
21 465.015, 465.0196, 468.812, 499.003, F.S.;
22 conforming cross-references; amending s.
23 499.012, F.S.; redefining the term "wholesale
24 distribution," relating to the distribution of
25 prescription drugs, to provide for the
26 exclusion of certain activities; creating s.
27 499.072, F.S.; creating the Drug Regulation
28 Advisory Group; providing membership; providing
29 terms of office; providing for meetings, for
30 reimbursement of expenses, and for purposes and
31 duties of the group; authorizing the Department

1 of Health to publish compliance policy
2 guidelines that include recommendations of the
3 group; providing effective dates.
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5 Be It Enacted by the Legislature of the State of Florida:
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7 Section 1. Present subsection (12) of section 465.003,
8 Florida Statutes, is renumbered as subsection (13) and
9 amended, present subsections (4) through (14) are renumbered
10 as subsections (5) through (15), respectively, and a new
11 subsection (4) is added to that section, to read:

12 465.003 Definitions.--As used in this chapter, the
13 term:

14 (4) "Data communication device" means an electronic
15 device that receives electronic information from one source
16 and transmits or routes it to another, including, but not
17 limited to, any such bridge, router, switch, or gateway.

18 (13)~~(12)~~ "Practice of the profession of pharmacy"
19 includes compounding, dispensing, and consulting concerning
20 contents, therapeutic values, and uses of any medicinal drug;
21 and consulting concerning therapeutic values and interactions
22 of patent or proprietary preparations, whether pursuant to
23 prescriptions or in the absence and entirely independent of
24 such prescriptions or orders; and other pharmaceutical
25 services. For purposes of this subsection, "other
26 pharmaceutical services" means evaluation and monitoring of
27 the patient's health as it relates to drug therapy and
28 assisting the patient in the management of his or her drug
29 therapy, and includes review of the patient's drug therapy and
30 communication with the patient and the patient's prescribing
31 health care provider as licensed under chapter 458, chapter

1 459, chapter 461, or chapter 466, or similar statutory
2 provision in another jurisdiction, or such provider's agent or
3 such other persons as specifically authorized by the patient,
4 regarding the drug therapy. However, nothing in this
5 subsection may be interpreted to permit an alteration of a
6 prescriber's directions, unless otherwise permitted by law.
7 "Practice of the profession of pharmacy"~~The phrase~~ also
8 includes any other act, service, operation, research,or
9 transaction incidental to, or forming a part of, any of the
10 foregoing acts, requiring, involving, or employing the science
11 or art of any branch of the pharmaceutical profession, study,
12 or training, and shall expressly permit a pharmacist to
13 transmit information from persons authorized to prescribe
14 medicinal drugs to their patients. "Practice of the
15 profession of pharmacy" also includes the administering of
16 immunizations by a pharmacist within the framework of an
17 established protocol under a supervisory practitioner who is a
18 physician licensed under chapter 458 or chapter 459 or by
19 written agreement with a county health department. Each
20 protocol must contain specific procedures to address any
21 unforeseen allergic reaction to an immunization. A pharmacist
22 may not enter into a protocol unless he or she maintains at
23 least \$200,000 of professional liability insurance, and not
24 until the pharmacist has completed training in immunizations
25 as may be required by the board. The decision by a
26 supervisory practitioner to enter into such a protocol is a
27 professional decision of the practitioner, and no person may
28 interfere with a supervisory practitioner's decision as to
29 whether to enter into such a protocol. A pharmacist may not
30 enter into a protocol that is to be performed while acting as
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1 an employee without the written approval of the owner of the
2 pharmacy.

3 Section 2. Effective upon this act becoming a law,
4 paragraph (1) of subsection (1) of section 465.016, Florida
5 Statutes, is amended to read:

6 465.016 Disciplinary actions.--

7 (1) The following acts shall be grounds for
8 disciplinary action set forth in this section:

9 (1) Placing in the stock of any pharmacy any part of
10 any prescription compounded or dispensed which is returned by
11 a patient; however, in a hospital, nursing home, correctional
12 facility, or extended care facility in which unit-dose
13 medication is dispensed to inpatients, each dose being
14 individually sealed and the individual unit dose or unit-dose
15 system labeled with the name of the drug, dosage strength,
16 manufacturer's control number, and expiration date, if any,
17 the unused unit dose of medication may be returned to the
18 pharmacy for redispensing. Each pharmacist shall maintain
19 appropriate records for any unused or returned medicinal
20 drugs.

21 Section 3. Paragraph (q) is added to subsection (1) of
22 section 465.016, Florida Statutes, to read:

23 465.016 Disciplinary actions.--

24 (1) The following acts shall be grounds for
25 disciplinary action set forth in this section:

26 (q) Using or releasing a patient's records except as
27 authorized by this chapter and chapter 455.

28 Section 4. Subsection (2) of section 465.017, Florida
29 Statutes, is amended to read:

30 465.017 Authority to inspect.--

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1 (2) Except as permitted by this chapter, and chapters
2 406, 409, 455, 499, and 893, records maintained by in a
3 pharmacy relating to the filling of prescriptions and the
4 dispensing of medicinal drugs shall not be furnished, except
5 upon the written authorization of the patient, to any person
6 other than to the patient for whom the drugs were dispensed,
7 ~~or her or his legal representative, or to the department~~
8 ~~pursuant to existing law,~~ or, in the event that the patient is
9 incapacitated or unable to request such said records, her or
10 his spouse; to the department pursuant to law; to health care
11 practitioners and pharmacists consulting with or dispensing to
12 the patient; or to insurance carriers or other payors
13 authorized by the patient to receive such records. For
14 purposes of this section, records held in a pharmacy shall be
15 considered owned by the owner of the pharmacy. The pharmacy
16 owner may use such records in the aggregate without patient
17 identification data, regardless of where such records are
18 held, for purposes reasonably related to the business and
19 practice of pharmacy ~~except upon the written authorization of~~
20 ~~such patient.~~ Such records may be furnished in any civil or
21 criminal proceeding, upon the issuance of a subpoena from a
22 court of competent jurisdiction and proper notice to the
23 patient or her or his legal representative by the party
24 seeking such records. Such records or any part thereof, if
25 transmitted through a data communication device and not
26 directly between a pharmacy and a treating practitioner, may
27 not be accessed, used, or maintained by the operator or owner
28 of the data communication device unless specifically
29 authorized by this section. It is the intent of this
30 subsection to allow the use and sharing of such records to
31 improve patient care, provided the pharmacist acts in the best

1 interests of her or his patient. Nothing in this subsection
2 may be construed to authorize or expand solicitation or
3 marketing to patients or potential patients in any manner not
4 otherwise specifically authorized by law.

5 Section 5. Section 465.014, Florida Statutes, is
6 amended to read:

7 465.014 Pharmacy technician.--No person other than a
8 licensed pharmacist or pharmacy intern may engage in the
9 practice of the profession of pharmacy, except that a licensed
10 pharmacist may delegate to nonlicensed pharmacy technicians
11 those duties, tasks, and functions which do not fall within
12 the purview of s. 465.003(13)~~(12)~~. All such delegated acts
13 shall be performed under the direct supervision of a licensed
14 pharmacist who shall be responsible for all such acts
15 performed by persons under his or her supervision. A pharmacy
16 technician, under the supervision of a pharmacist, may
17 initiate or receive communications with a practitioner or his
18 or her agent, on behalf of a patient, regarding refill
19 authorization requests. No licensed pharmacist shall
20 supervise more than one pharmacy technician unless otherwise
21 permitted by the guidelines adopted by the board. The board
22 shall establish guidelines to be followed by licensees or
23 permittees in determining the circumstances under which a
24 licensed pharmacist may supervise more than one but not more
25 than three pharmacy technicians.

26 Section 6. Paragraph (c) of subsection (2) of section
27 465.015, Florida Statutes, is amended to read:

28 465.015 Violations and penalties.--

29 (2) It is unlawful for any person:
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1 (c) To sell or dispense drugs as defined in s.
2 465.003(8)~~(7)~~ without first being furnished with a
3 prescription.

4 Section 7. Section 465.0196, Florida Statutes, is
5 amended to read:

6 465.0196 Special pharmacy permits.--Any person
7 desiring a permit to operate a pharmacy which does not fall
8 within the definitions set forth in s. 465.003(11)~~(10)~~(a)1.,
9 2., and 3. shall apply to the department for a special
10 pharmacy permit. If the board certifies that the application
11 complies with the applicable laws and rules of the board
12 governing the practice of the profession of pharmacy, the
13 department shall issue the permit. No permit shall be issued
14 unless a licensed pharmacist is designated to undertake the
15 professional supervision of the compounding and dispensing of
16 all drugs dispensed by the pharmacy. The licensed pharmacist
17 shall be responsible for maintaining all drug records and for
18 providing for the security of the area in the facility in
19 which the compounding, storing, and dispensing of medicinal
20 drugs occurs. The permittee shall notify the department
21 within 10 days of any change of the licensed pharmacist
22 responsible for such duties.

23 Section 8. Subsection (3) of section 468.812, Florida
24 Statutes, is amended to read:

25 468.812 Exemptions from licensure.--

26 (3) The provisions of this act relating to orthotics
27 or pedorthics do not apply to any licensed pharmacist or to
28 any person acting under the supervision of a licensed
29 pharmacist. The practice of orthotics or pedorthics by a
30 pharmacist or any of the pharmacist's employees acting under
31 the supervision of a pharmacist shall be construed to be

1 within the meaning of the term "practice of the profession of
2 pharmacy" as set forth in s. 465.003(13)(~~12~~), and shall be
3 subject to regulation in the same manner as any other pharmacy
4 practice. The Board of Pharmacy shall develop rules regarding
5 the practice of orthotics and pedorthics by a pharmacist. Any
6 pharmacist or person under the supervision of a pharmacist
7 engaged in the practice of orthotics or pedorthics shall not
8 be precluded from continuing that practice pending adoption of
9 these rules.

10 Section 9. Subsection (19) of section 499.003, Florida
11 Statutes, is amended to read:

12 499.003 Definitions of terms used in ss.

13 499.001-499.081.--As used in ss. 499.001-499.081, the term:

14 (19) "Legend drug," "prescription drug," or "medicinal
15 drug" means any drug, including, but not limited to, finished
16 dosage forms, or active ingredients subject to, defined by, or
17 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
18 Act or s. 465.003(8)(~~7~~), s. 499.007(12), or s. 499.0122(1)(b)
19 or (c).

20 Section 10. Paragraph (a) of subsection (1) and
21 subsection (5) of section 499.012, Florida Statutes, 1998
22 Supplement, are amended to read:

23 499.012 Wholesale distribution; definitions; permits;
24 general requirements.--

25 (1) As used in this section, the term:

26 (a) "Wholesale distribution" means distribution of
27 prescription drugs to persons other than a consumer or
28 patient, but does not include:

29 1. Any of the following activities, which is not a
30 violation of s. 499.005(21) if such activity is conducted in
31 accordance with s. 499.014:

1 a. The purchase or other acquisition by a hospital or
2 other health care entity that is a member of a group
3 purchasing organization of a prescription drug for its own use
4 from the group purchasing organization or from other hospitals
5 or health care entities that are members of that organization.

6 b. The sale, purchase, or trade of a prescription drug
7 or an offer to sell, purchase, or trade a prescription drug by
8 a charitable organization described in s. 501(c)(3) of the
9 Internal Revenue Code of 1986, as amended and revised, to a
10 nonprofit affiliate of the organization to the extent
11 otherwise permitted by law.

12 c. The sale, purchase, or trade of a prescription drug
13 or an offer to sell, purchase, or trade a prescription drug
14 among hospitals or other health care entities that are under
15 common control. For purposes of this section, "common control"
16 means the power to direct or cause the direction of the
17 management and policies of a person or an organization,
18 whether by ownership of stock, by voting rights, by contract,
19 or otherwise.

20 2. Any of the following activities, which is not a
21 violation of s. 499.005(21) if such activity is conducted in
22 accordance with rules established by the department:

23 a. The sale, purchase, or trade of a prescription drug
24 among federal, state, or local government health care entities
25 that are under common control and are authorized to purchase
26 such prescription drug.

27 b. The sale, purchase, trade, or other transfer of a
28 prescription drug from or for any federal, state, or local
29 government agency or any entity eligible to purchase
30 prescription drugs at public health services prices pursuant
31 to s. 602 of Pub. L. No. 102-585 to a contract provider or its

1 subcontractor for eligible patients of the agency or entity
2 under the following conditions:

3 (I) The agency or entity must obtain written
4 authorization for the sale, purchase, trade, or other transfer
5 of a prescription drug under this sub-subparagraph from the
6 Secretary of Health. This written authorization must be based
7 on a favorable recommendation by the Drug Regulation Advisory
8 Group after the group has reviewed the agency's or entity's
9 submission to the department of a detailed plan and
10 justification for the sale, purchase, trade, or other transfer
11 of a prescription drug under this sub-subparagraph and must
12 enhance the public's health by improving needed access,
13 quality, or safety because current patient drug delivery
14 systems are inadequate.

15 (II) The contract provider or subcontractor must be
16 authorized by law to administer or dispense prescription
17 drugs.

18 (III) In the case of a subcontractor, the agency or
19 entity must be a party to and execute the subcontract.

20 (IV) A contract provider or subcontractor must
21 maintain separate and apart from other prescription drug
22 inventory any prescription drugs of the agency or entity in
23 its possession.

24 (V) The contract provider and subcontractor must
25 maintain and produce immediately for inspection all records of
26 movement or transfer of all the prescription drugs belonging
27 to the agency or entity, including, but not limited to, the
28 records of receipt and disposition of prescription drugs.
29 Each contractor and subcontractor dispensing or administering
30 these drugs must maintain and produce records documenting the
31 dispensing or administration. Records that are required to be

1 maintained include, but are not limited to, a perpetual
2 inventory itemizing drugs received and drugs dispensed by
3 prescription number or administered by patient identifier,
4 which must be submitted to the agency or entity monthly.

5 (VI) The contract provider or subcontractor may
6 administer or dispense the prescription drugs only to the
7 eligible patients of the agency or entity or must return the
8 prescription drugs for or to the agency or entity. The
9 contract provider or subcontractor must require proof from
10 each person seeking to fill a prescription or obtain treatment
11 that the person is an eligible patient of the agency or entity
12 and must, at a minimum, maintain a copy of this proof as part
13 of the records of the contractor or subcontractor required
14 under sub-sub-subparagraph (V).

15 (VII) The prescription drugs transferred pursuant to
16 this sub-subparagraph may not be billed to Medicaid.

17 (VIII) In addition to the departmental inspection
18 authority set forth in s. 499.051, the establishment of the
19 contract provider and subcontractor and all records pertaining
20 to prescription drugs subject to this sub-subparagraph shall
21 be subject to inspection by the agency or entity. All records
22 relating to prescription drugs of a manufacturer under this
23 sub-subparagraph shall be subject to audit by the manufacturer
24 of those drugs, without identifying individual patient
25 information.

26 c.b. The sale, purchase, or trade of a prescription
27 drug or an offer to sell, purchase, or trade a prescription
28 drug for emergency medical reasons.† For purposes of this
29 sub-subparagraph ~~subparagraph~~, the term "emergency medical
30 reasons" includes transfers of prescription drugs by a retail
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1 pharmacy to another retail pharmacy to alleviate a temporary
2 shortage.

3 ~~d.c.~~ The transfer purchase or acquisition of a
4 prescription drug acquired by a medical director on behalf of
5 a licensed an emergency medical services provider to that
6 ~~medical director for use by~~ emergency medical services
7 provider and its transport vehicles for use in accordance with
8 the provider's license under providers acting within the scope
9 ~~of their professional practice pursuant to~~ chapter 401.

10 ~~e.d.~~ The revocation of a sale or the return of a
11 prescription drug to the person's prescription drug wholesale
12 supplier.

13 ~~f.e.~~ The donation of a prescription drug by a health
14 care entity to a charitable organization that has been granted
15 an exemption under s. 501(c)(3) of the Internal Revenue Code
16 of 1986, as amended, and that is authorized to possess
17 prescription drugs.

18 ~~g.f.~~ The transfer of a prescription drug by a person
19 authorized to purchase or receive prescription drugs to a
20 person licensed or permitted to handle reverse distributions
21 or destruction under the laws of the jurisdiction in which the
22 person handling the reverse distribution or destruction
23 receives the drug.

24 ~~3. The dispensing of a prescription drug pursuant to a~~
25 ~~prescription;~~

26 ~~h.4.~~ The distribution of prescription drug samples by
27 manufacturers' representatives or distributors'
28 representatives conducted in accordance with s. 499.028. ~~or~~

29 ~~i.5.~~ The sale, purchase, or trade of blood and blood
30 components intended for transfusion. As used in this
31 sub-subparagraph ~~section~~, the term "blood" means whole blood

1 collected from a single donor and processed either for
2 transfusion or further manufacturing, and the term "blood
3 components" means that part of the blood separated by physical
4 or mechanical means.

5 3. The lawful dispensing of a prescription drug in
6 accordance with chapter 465.

7 (5) The department may adopt rules governing the
8 recordkeeping, storage, and handling with respect to each of
9 the distributions of prescription drugs specified in
10 subparagraphs (1)(a)1. ~~and 2., 4., and 5.~~

11 Section 11. Section 499.072, Florida Statutes, is
12 created to read:

13 499.072 Drug Regulation Advisory Group.--

14 (1) There is created the Drug Regulation Advisory
15 Group, which is an independent advisory group composed of at
16 least 13 members appointed by the Secretary of Health and
17 including:

18 (a) One member representing the prescription drug
19 wholesale industry in this state.

20 (b) One member representing pharmaceutical
21 manufacturers, who may represent pharmaceutical manufacturers
22 nationwide.

23 (c) One member who is a practicing pharmacist.

24 (d) One member representing the Agency for Health Care
25 Administration.

26 (e) One member who is a physician licensed under
27 chapter 458 or chapter 459.

28 (f) One consumer representative.

29 (g) One member representing the cosmetic industry.

30 (h) One member representing the compressed medical gas
31 industry.

1 (i) One member representing the medical device
2 manufacturing industry.

3 (j) The Executive Director of the Board of Pharmacy,
4 who shall be an ex officio member.

5 (k) One member representing the department, who shall
6 chair group meetings.

7 (l) One member representing hospitals.

8 (m) One member representing the long-term care
9 industry.

10 (2) Members shall be appointed for terms of 4 years,
11 except for the Executive Director of the Board of Pharmacy and
12 the departmental representative, who may serve indefinitely.
13 Members of the group may be reappointed. A vacancy in
14 membership that occurs before the expiration of a term shall
15 be filled by a member appointed by the Secretary of Health for
16 a full term.

17 (3) The group shall meet upon request of the
18 department, but no more than four times a year. Members of
19 the group shall serve without compensation, but may be
20 reimbursed for per diem and travel expenses as provided in s.
21 112.061.

22 (4) The purposes and duties of the Drug Regulation
23 Advisory Group include, but are not limited to:

24 (a) Making recommendations to the Secretary of Health
25 regarding authorizations for the sale, purchase, trade, or
26 other transfer of a prescription drug under s. 499.012(1)(a)2.

27 (b) Making recommendations to the department regarding
28 enforcement priorities under this chapter.

29 (c) Briefing the department on industry trends that
30 affect this chapter.

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1 (d) Providing information and guidance on issues
2 submitted by the department to the group.

3 (e) Facilitating the dissemination of relevant
4 information concerning current issues affecting the public
5 health within the scope and responsibility of this chapter.

6 (5) The department may publish compliance policy
7 guidelines that set forth enforcement priorities or other
8 recommendations of the Drug Regulation Advisory Group when
9 that is in the best interests of the public health.

10 Section 12. Except as otherwise provided in this act,
11 this act shall take effect July 1, 1999.

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14 LEGISLATIVE SUMMARY

15 Defines the term "data communication device" and expands
16 the definition of "practice of the profession of
17 pharmacy" to include other pharmaceutical services
18 relating to drug therapy and administration of
19 immunizations under certain circumstances. Authorizes
20 the redispensing of unused or returned unit-dose
21 medication by correctional facilities under certain
22 conditions. Provides that using or releasing a patient's
23 records except as authorized by chapter 465 or chapter
24 455, F.S., constitutes a ground for disciplinary action
25 against a pharmacist. Provides additional persons to
26 whom and entities to which records relating to the
27 filling of prescriptions and the dispensing of medicinal
28 drugs that are maintained by a pharmacy may be furnished.
29 Specifies authorized uses of patient records by pharmacy
30 owners. Provides restrictions on such records when
31 transmitted through a data communication device.
Redefines the term "wholesale distribution," relating to
the distribution of prescription drugs, to provide for
the exclusion of certain activities. Creates the Drug
Regulation Advisory Group and provides for its members
and their terms of office. Provides for meetings, for
reimbursement of expenses, and for purposes and duties of
the group. Authorizing the Department of Health to
publish compliance policy guidelines that include
recommendations of the group. (See bill for details.)